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(54) Title: DIAGNOSTIC METHOD FOR CELIAC SPRUE

(57) Abstract: Detection of toxic gluten oligopeptides refractory to digestion and antibodies and T cells responsive thereto can be used to diagnose Celiac Sprue.

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/37434

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(7) : G01N 33/53  
 US CL : 435/7.1, 7.94; 436/506, 513

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
 U.S. : 435/7.1, 7.94; 436/506, 513

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6,319,726 B1 (Schuppan et al.) 20 November 2001 (20.11.2001), abstract, particularly on using antibody to detect tTG transglutaminase.	12-28
Y	US 2001/0036639 A1 (FINE) 01 November 2001 (01.11.2001), see whole document.	12-28
Y	WO 200125793 A2 (ISIS INNOVATION LIMITED) 12 April 2001(12.04.2001), abstract, similar methodology using gliadin derived peptide to detect celiac sprue disease, albeit no homology (74%) compared to SEQ ID No. 12 of the instant invention.	12-28

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier application or patent published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means		
"P" document published prior to the international filing date but later than the priority date claimed		

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Name and mailing address of the ISA/US

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**INTERNATIONAL SEARCH REPORT**

International Application No.

PCT/US03/37434

**Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)**

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claim Nos.: because they relate to subject matter not required to be searched by this Authority, namely:
  
2.  Claim Nos.: 1-11 because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:  
Please See Continuation Sheet
  
3.  Claim Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1.  As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.  As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
  
4.  No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**     The additional search fees were accompanied by the applicant's protest.  
                             No protest accompanied the payment of additional search fees.

**INTERNATIONAL SEARCH REPORT**

PCT/US03/37434

**Continuation of Box I Reason 2:**

Claim 1, directs to a purified glucent oligopeptide, having the formula :

E1-X1-E2-X2-E3..... Xn-Ey.

Where E1, E2 and E3 are independently selected epitopes from SEQ ID No. 10, 18-25.

X1 and X2 are independently selected from the group consisting of a peptide bond and at least one amino acid, n=0-5, and y=0-5.

With such a complicated structure, it is estimated that there are at least more than 10000 different combination. It imposes an undue burden for sequence search. Therefore, the current search is conducted only for claims 12-28.